REMARKS

I. Preliminary Remarks

In the Office Action, Claims 1-51 are pending and under examination. All claims are subject to a requirement for restriction. After entry of this paper, Claims 1-13 are under consideration. Claims 14-51 are withdrawn, with traverse and without prejudice in an effort to favorably advance prosecution of the present application. Applicants reserve the right to petition for rejoinder should the circumstances allow, or to pursue the subject matter of the withdrawn claims in divisional applications. However, reconsideration and withdrawal of the restriction requirement are solicited for the reasons set out below.

Applicants respectfully submit that Claims 29-34, even though depending from Claim 14 which is in Group II, should properly be in Group III because they relate to a combination vaccine comprising a *Leptospira* cell preparation of at least one of *Leptospira bratislava*, *Leptospira canicola*, *Leptospira grippotyphosa*, *Leptospira icterhaemorrhagiae*, or *Leptospira pomona*.

This Response addresses the Examiner's restriction requirement. Applicants therefore respectfully submit that the present application is in condition for examination on the merits. Favorable consideration of all pending claims is respectfully requested.

This Response is timely filed. The USPTO is given authorization to charge Deposit Account No. 21-0718 for any fees necessary with the submission of this Response.

II. Remarks/Arguments

In the Office Action, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following three separate and distinct inventions:

I. Claims 1-13, drawn to a vaccine composition comprising an amount of a B. bronchiseptica p68 antigen and an adjuvant and methods of protecting dogs against B. bronchiseptica, classified in class 424, subclass 253.1.

II. Claims 14-34, drawn to a combination vaccine for immunizing dogs against canine pathogens comprising a preparation of an attenuated strain of canine distemper (CD) virus, an attenuated strain of canine adenovirus type 2 (CAV-2), an attenuated strain of canine parainfluenza (CPI) virus and an attenuated strain of

canine parvovirus (CPV); an inactivated whole or partial cell preparation of a strain of canine coronavirus (CCV), B. bronchiseptica p68 antigen and an adjuvant and methods of immunization using said vaccine, classified in class 424, subclass 201.1.

III. Claim 35-51, drawn to a combination vaccine for immunizing dogs against canine pathogens comprising a preparation of an attenuated strain of canine distemper (CD) virus, an attenuated strain of canine adenovirus type 2 (CAV-2), an attenuated strain of canine parainfluenza (CPI) virus and an attenuated strain of canine parvovirus (CPV); a Bordetella bronchiseptica p68 protein, a Leptospira bacterin which comprises a cell preparation of at least one of Leptospira bratislava, Leptospira canicola, Leptospira grippotyphosa, Leptospira icterhaemorrhagiae, or Leptospira pomona; and an adjuvant, classified in class 424, subclass 203.1.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group I, Claims 1-13, drawn to a vaccine composition comprising an amount of a B. bronchiseptica p68 antigen and an adjuvant and methods of protecting dogs against B. bronchiseptica, classified in class 424, subclass 253.1.

Applicants conditionally withdraw Claims 14-51 with traverse and without prejudice. Applicants reserve the right to petition for rejoinder by way of amendment pursuant to 37 CFR 1.121 should the circumstances allow, or file one or more divisional applications directed to the non-elected subject matter in this Application.

However, pursuant to 37 CFR 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" enough so as to justify the restriction requirement. In addition, for the Groups to be unrelated, it must be shown that "they are not disclosed as capable of use together." However, each of the Groups contains B. bronchiseptica p68 antigen. Group II additionally contains viral antigens, and Group III contains viral antigens and a *Leptospira* cell preparation.

The courts have recognized that it is in the public interest to permit Applicants to claim several aspects of their invention together in one application, as the Applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. § 112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl 456 F.2d 658, 666, 117 U.S.P.Q. 250,256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

In addition, this restriction is improper because prosecution of the restricted subject matter in one application would not place a serious burden on the Examiner. According to MPEP § 803, the Examiner can only restrict patentably distinct inventions when (1) the inventions are independent or distinct as claimed; and (2) where there is a serious burden on the Examiner if restriction is not required. Applicants respectfully submit that the Examiner has made no showing that prosecuting the claims of the invention in one application would be burdensome. Groups I-III are all directed to similar subject matter. In fact, the Groups are directed to the same class. Therefore, it is respectfully submitted that it would not constitute undue burden on the Examiner for the claims of all the groups to be maintained in a single application and for all three groups to be examined together. It is respectfully submitted that prosecution of all of these

groups of claims in a single application would be efficient, thereby promoting the grounds for the establishment of the restriction requirement practice.

Applicants further respectfully suggest that in view of the continued increase of official fees and the potential limitation of Applicants' financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

III. Conclusion

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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